American Academy of Dermatology

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MANAGEMENT BRANCH

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

In Re: Docket No. *93N-0044*

Dear Sirs:

I am writing on behalf of the American Academy of Dermatology to comment on your notice entitled, "Laser Products; Intent to Amend Performance Standard," which was published in the May 10, 1993 issue of the *Federal Register [58 Fed. Reg. 27495].* According to the notice, the Food and Drug Administration (FDA) is considering amendments to the federal performance standard for laser products.

The Academy has a special interest in this notice. As you know, the Academy is the medical specialty society for physicians specializing in diseases of the skin, hair and nails. The Academy is committed to promoting the highest possible standards in clinical practice and enhancing quality patient care. To this end, the use of laser products in the treatment of certain skin diseases has proved to be safe and effective. For these reasons, the Academy has a special interest in this matter.

Our principal concern with the amendments under consideration lies in paragraph 18 of section II on page 27497, As presented, the wording is unclear. The amendment under consideration would require optical or electrical monitoring of the operation of lasers in Class IIIb and Class IV medical laser products. The proposed amendment states that:

> "...an additional means of monitoring would be required for those laser products in which the output is only measured occasionally, such as before a procedure or between patient exposures."

For very low repetition rate pulsed laser systems, the energy is usually measured before a procedure begins or between patient exposures. If an additional means of monitoring is

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required beyond the level of normal compliance, the "additional means" would be a significant engineering feat. This is because "real-time" monitoring of the pulsed energy during an actual treatment pulse requires an instantaneous shattering or shut-off of the laser pulse while the specified energy has been reached. For that reason, further clarification of this possible would

revision would certainly be appropriate. If this engineering change would be required for new or existing laser systems, the cost of new pulsed laser systems would be extraordinarily increased.

I hope these comments are helpful. If you have any questions or need additional information, please do not hesitate to contact me.

Sincerely,

Mark V. Dahl, M.D.
President

MVD/br

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